

## **REMARKS**

### **Claim Amendments**

The withdrawn claims have been cancelled without prejudice or disclaimer.

Independent claims 1 and 5 have been cancelled without prejudice or disclaimer.

Claims 2 and 6 have been rewritten in independent form and the other claims are dependent thereon.

Applicants respectfully request the entry of these amendments as they do not raise any new issues.

### **Priority**

The Office Action alleges that 35 USC § 119(b) requires a certified copy of the English translation of the foreign priority application. This allegation is incorrect. Section 119(b) uses the term “may” require a translation. Typically, a translation is submitted by an applicant when a foreign language priority document is used to predate a prior art reference.

### **The Rejections Under 35 USC § 103**

The Office Action cites two references and alleges that each reference teaches one component of the claimed composition.

Nowhere does the Office Action teach why one of ordinary skill in the art would have selected the two recited specific components in the claimed invention. This is especially so since nowhere does Krattenmacher disclose that a joint administration with an androgen is useful for male contraception.

Nevertheless, even assuming that one of ordinary skill in the art would have selected these two references among the many potential references disclosing various compounds for contraception (for which there is no specific reason other than a generic overlap in broad indications), there would still be a prohibitively large number of options (species) within these references to render obvious the claimed invention.

For example, CA ‘605 identifies a very large number of species (i.e., 76 compounds) extending through about four pages in length (see, e.g., pages 4-8). Also, the primary reference discloses 9 species (see, e.g., claim 8). Without any guidance toward the selection of the specific compounds recited in the present claims, one of ordinary skill in the art would not have reasonably achieved the claimed invention. For example, even assuming the field

would have been narrowed down to these two references, the chance that one of ordinary skill in the art would have ended up with the claimed combination is very small, i.e., one in nearly seven hundred (9 x 76). Once one would consider the other potential compounds in the art for combinations, this number would increase to even much higher.

Applicants also point to page 9, first full paragraph, teaching that

With the application of the above-mentioned combination as a male contraceptive agent, an adequate inhibition of the sperm production in the testes can be achieved with a relatively low substitution dose of the androgen at the same time. In this connection, a synergistic effect is achieved.

Such synergistic effect could not have been predicted based on the teachings of the prior art.

Additionally, the application provides data on pages 11-12 and in figures 1-2 demonstrating the effectiveness of the claimed combination.

For all the foregoing reasons, reconsideration is respectfully requested.

### **The Rejections Under 35 USC § 112**

The rejections to the form of the claims to the extent not discussed below are moot in view of the amendments to the claims.

In points 2 and 3 on page 10 of the Office Action claims 7-12 are alleged to be indefinite because it is allegedly unclear whether both components of the combination are required to be formulated the same. There is no indefiniteness in the claims. These claims do not recite a "composition" that is inseparable, but a "combination" where the individual components can be, e.g., provided as two individually and independently formulated elements, e.g., one part being orally formulated, while the other being provided in an implantable extended release formulation. However, the two components can be in the same type of formulation or in the same formulation.

### **Comments on the Notes to the Applicants**

The Office Action alleges that the terms "such that" and "suitable for" are "optional language," i.e., that said language "suggests or makes optional" the material that follow. Applicants respectfully disagree. These terms are positive recitations without room for them being optional. The common usage of these terms also does not invoke any suggestions of

optionality. Moreover, applicants are unaware of a case where these terms in a context as the present one would have been held to suggest or make optional the language that follows.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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